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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,335	05/20/2008	Philippe Perovitch	0603-1002	2717

466 7590 10/21/2010

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EXAMINER	
MELLER, MICHAEL V	
ART UNIT	PAPER NUMBER
1655	

NOTIFICATION DATE	DELIVERY MODE
10/21/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary	Application No.	Applicant(s)	
	10/585,335	PEROVITCH ET AL.	
	Examiner	Art Unit	
	Michael V. Meller	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 August 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *11, 12, 20* is/are allowed.

6)☒ Claim(s) *1-10 and 13-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of **pilocarpine in the salt form, methylcellulose, sorbitol, sodium or disodium hydrogen phosphate , magnesium stearate, polyethylene glycol, hyaluronic acid, lysozyme chlorohydrate (aka lysozyme-see below explanation)** in the reply filed on 4/13/2010 is acknowledged. The traversal is on the ground(s) that the JP 07330602 reference cited previously does not apply to the instant claims under the PCT rules. This is not found persuasive because as noted on the record, the claims are properly rejected under the cited art. Thus, a lack of unity does indeed exist. The art does teach the salt form of pilocarpine and a bioadhesive polymer such as the elected methylcellulose. The claims are being examined for the above specifically elected composition.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the

subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-10, 13-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singh et al. (US 2003/0185884) in view of Frey, II (US 2001/0043915), GB 941664 and Hatsuya et al. (US 5342840) and as evidenced by "Resolution Oeno".

Singh teaches that pilocarpine and its salts are known to be formulated into a dissolving tablet, chewing tablet or the like to be used orally in the buccal cavity, see paragraphs 35, 55, 81, 84, 110, 117, abstract and the claims. Sorbitol and magnesium stearate are also used in the tablet.

Singh does not teach using hyaluronic acid, methylcellulose, lysozyme chlorohydrate, polyethylene glycol or disodium hydrogen phosphate.

Frey teaches that hyaluronic acid is used for buccal administration in tablet form, see paragraphs 86, 89.

Hatsuya teaches that methylcellulose, polyethylene glycol and disodium hydrogen phosphate are all well known common pharmaceutical components and are also used in tablet form, see col. 11, lines 27-end.

GB teaches that lysozyme which is the same as lysozyme chlorohydrate (see "Resolution Oeno") is used in sublingual tablet form, see entire reference.

It would have been obvious to one having ordinary skill in the art to use all of the claimed components together since they are known to be used in a tablet.

It is well known that it is *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Sussman,* 136 F.2d 715, 718, 58 USPQ 262, 264 (CCPA 1943); *In re Pinten*, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). *In re Kerkhoven*, 626 F. 2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose).

> The reason or motivation to modify a reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. While there must be motivation to make the claimed invention, there is no requirement that the prior art provide the same reason as the applicant to make the claimed invention.
>
> MPEP 2144 Sources of Rationale Supporting a Rejection Under 35 U.S.C. 103. <http://www.uspto.gov/web/offices/pac/mpep/documents/2100_2144.htm>

Indeed, the tablet is known to be in a form for sublingual administration, see Frey, GB and Singh. Thus, it was clearly within the purview of the ordinary artisan to use all of the components together to be in a single tablet used for sublingual administration.

Applicant argues in their response filed 8/11/2010 that Singh allegedly teaches that pilocarpine is in lipophilic form. Applicant argues that one of ordinary skill in the art would recognize that pilocarpine is not lipophilic. Applicant argues that pilocarpine is amphiphilic. Then, applicant concludes that allegedly Singh incorrectly teaches that a pH buffer would turn an amphiphilic substance into a lipophilic one. While this is noted, it is also noted that pilocarpine is still being used by Singh. Whether applicant wants to call it an amphiphilic substance versus what Singh calls it, a lipophilic one, it is still the same compound, pilocarpine.

Applicant next alleges that Singh fails to teach or suggest any specific sublingual form or application of pilocarpine that would bring local effectiveness to the mucous floor. This is incorrect since Singh clearly teaches tablets in paragraph 55. Applicant also claims tablets thus the argument is moot.

Applicant alleges that their composition is a slow and local coating/releasing galenic structure allowing for a local mucous fixation/passage of the amphiphilic freely soluble drug. Singh also teaches a sublingual tablet which would act the same way as the claimed tablet. There is nothing on the record to prove that the tablet of Singh would not be expected to act as the instantly claimed tablet. Both the instantly claimed tablet and the one in Singh teach sublingual administration of a tablet, thus they both act the same way.

Next applicant argues that Frey allegedly teaches that the purpose of Frey and the instantly claimed invention are not one and the same. While this is noted, the instantly claimed invention and Frey do not have to have the same purpose, only Frey and Singh have to. Applicant next argues that Frey and Singh allegedly do not teach the same route of administration but clearly they both teach sublingual administration as noted above.

Applicant next argues that Hatsuya allegedly teaches tablet form but not any composition of cycloprane combined with at least one bioadhesive polymer so as to allow dissolution and local attachment to the tissues of the buccopharyngeal cavity. While this is noted it is not required. Hatsuya was cited to teach that methylcellulose, polyethylene glycol and disodium hydrogen phosphate are all well known common pharmaceutical components and are also used in tablet form, see col. 11, lines 27-end. Thus, Hatsuya does not have to teach a

composition of cycloprane combined with at least one bioadhesive polymer so as to allow dissolution and local attachment to the tissues of the buccopharyngeal cavity because Hatsuya teaches that methylcellulose, polyethylene glycol and disodium hydrogen phosphate can be used in a tablet and such a tablet can be made also with pilocarpine. Methylcellulose, polyethylene glycol, disodium hydrogen phosphate, and pilocarpine have all been shown to be in tablet form, thus to use methylcellulose, polyethylene glycol and disodium hydrogen phosphate all in tablet form is obvious as is of record. One does not have to prove that cycloprane and methylcellulose can be used together since Haysuya clearly establishes that methylcellulose, polyethylene glycol, and disodium hydrogen phosphate are used in tablets and Singh has already established that pilocarpine is used in tablet form as well, thus since they were used in the art for the same purpose, namely in tablet form, then it is obvious to combine them for the reasons of record.

The tablet in Hatsuya could be used as a sublingual tablet since a tablet is placed in the mouth and sublingual is under the tongue which is in the mouth, see col. 11, lines 25-60.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael V. Meller
Primary Examiner
Art Unit 1655

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